Lullaby

ALTERNATING DYNAMIC PRESSURE THERAPY SYSTEM

User Instructions

SIDHIL

www.sidhil.com

INTRODUCTION

Thank you for choosing a Sidhil Lullaby Alternating Dynamic Pressure Therapy System. This user manual should be read carefully before you use your mattress system as it contains important information regarding safe operation and maintenance in order to provide long lasting and reliable service.

Please ensure that you understand all the instructions, if you have any questions concerning the operation and maintenance of the mattress system please contact your supplier who will provide you with expert professional advice.

The Lullaby Alternating Dynamic Pressure Therapy System is intended to provide comfort and pressure relief to patients vulnerable to pressure damage. It is designed for use on the Sidhil Inspiration Cot. Ideally, patients allocated to this system will have some degree of independent mobility or can be repositioned according to individual needs.

The standard system DYN/TRIO/LULL incorporates an alternating mattress with static head section. An optional system DYN/TRIO/LULL/RP incorporates an alternating mattress with alternating head section

The maximum patient weight limit is 160kg (25 stone).

WARNING

Misused electrical equipment can be hazardous.

Accessories that have not been approved or designed for use with the system should not be used.

This electrically operated system should not be used in the presence of flammable gases or in operating theatres.

This product is not recommended for carrying patients during emergency evacuation.

In line with our policy of continuous improvement we welcome any suggestions that could lead to product improvement.

This product is manufactured to comply with the essential requirements of the Medical Devices Directive 93/42 EEC CE

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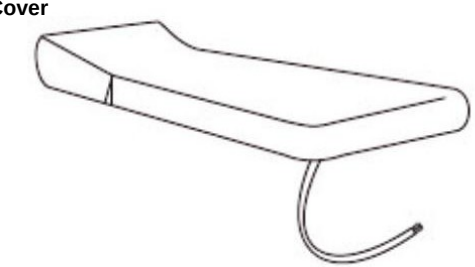
SECTION 1 GETTING STARTED

1.1 Parts list

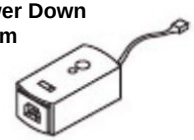
The transport carton contains everything you need to use your mattress. This includes:

- Mattress and Cover
- Power Unit
- Power Down Alarm
- Mains Lead
- Storage Bag (not shown)

Mattress and Cover



Power Down Alarm



Power Unit

Mains Lead

1.2 Setting up mattress and power unit on a bed frame

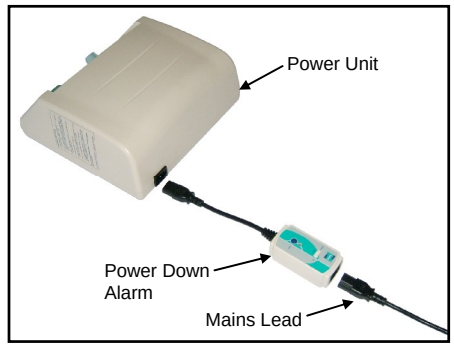
1. Remove the existing mattress from the bed frame and inspect the bed for any sharp areas which could damage your new mattress.

2. Remove the mattress from the packaging and place it onto the bed frame with the air pipe and power unit at the foot end and the 'foot' graphic facing upwards.

3. Hang the power unit on the foot board of the bed*, using the wire handles at the rear of the power unit. Connect the power down alarm to the power unit and connect the mains lead from the power down alarm to a suitable electrical socket outlet (see Figure 2).

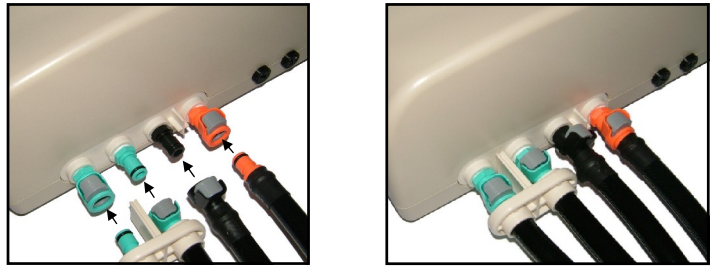
*If the bed does not have a foot board, place the power unit on the floor with the front of the unit facing upwards. Ensure the rear of the unit is not obstructed by carpet, rugs etc – it is advisable to place the unit on a firm surface.

Fig 2: Connecting the power unit to the mains supply



4. Connect the air pipes from the mattress to the power unit. Connect the pair of pipes with turquoise colour connector ends to the corresponding turquoise connectors on the power unit. The remaining two individual pipes should be clipped onto their corresponding coloured connectors on the power unit, i.e. black to black and orange to orange (see Figure 3).

Fig 3: Connecting mattress air pipes to power unit



WARNING

Ensure that the mains lead is not under tension when connected to the power supply.

Ensure that all cables and air supply pipes are clear of any moving parts on the bed to prevent them becoming tangled or damaged

5. Ensure that the CPR valve on the mattress umbilical has the pair of **white dots** aligned, as shown in Figure 4. This indicates that CPR mode **has not** been activated.

Fig 4: CPR 'dot' orientation

1.3 Switching system on and basic operation

Read all instructions below before use:

To reduce the risk of electrocution:

- Always unplug this product immediately after using
- Do not use while bathing
- Do not place or store product where it can fall or be pulled into a tub or sink
- Do not place in or drop into water or other liquid
- Do not use a product that has fallen into water. Unplug immediately

To reduce the risk of burns, electrocution, fire, or injury to persons:

- Some supervision may be necessary when used by or near children or the physically challenged
- Use this product only for its intended use as described in this manual. Do not use attachments not recommended by Sidhil Ltd
- Never operate this product if it has a damaged mains lead or plug. If it is not working properly or if it has been dropped or damaged in any way please contact your local authorised service personnel or Sidhil Ltd
- Keep the mains lead away from warm surfaces
- Never block the air filters on the power unit or place it on a soft surface, such as a bed or a couch, where the openings may be blocked
- Never drop or insert any objects into any tubing / openings

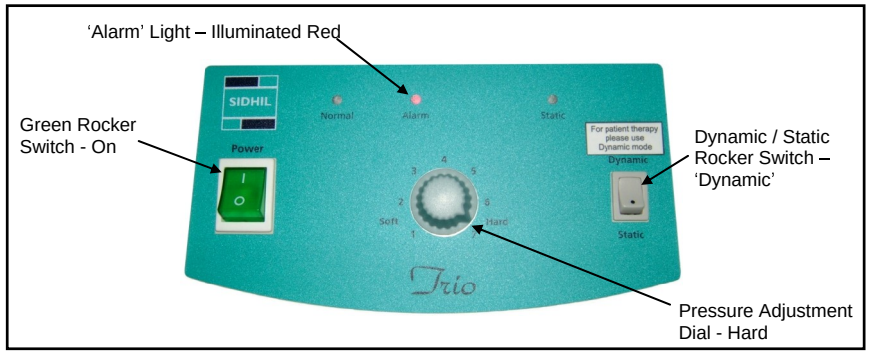
WARNING

This equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide.

Keep away from sources of heat and naked flames

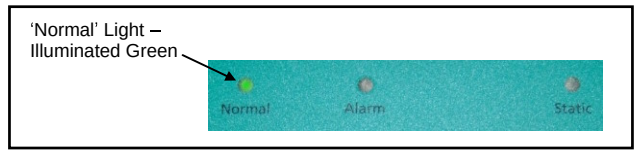
1. Before switching on the power unit turn the pressure adjustment dial to 'hard' and set the dynamic/static rocker switch to 'dynamic'. Switch on the power unit by depressing the green rocker switch. The 'alarm' light will now be illuminated red, the 'normal' and 'static' light indicators should not be illuminated (see Figure 5).

Fig 5: Initial setup of the power unit



2. The mattress will start to inflate. This process will take approximately 40 minutes. When the mattress is fully inflated the red alarm light will go out and the green light indicating 'normal' operation will be lit (see Figure 6).

Fig 6: Power unit indicator light



3. Once inflated, ensure that the mattress is correctly position on the bed.

4. Ensure that the mattress is always covered with a loose fitting bed sheet. **Before placing a patient onto the mattress refer to 'Setting the Optimum Pressure'.**

SECTION 2 POWER UNIT OPERATION

2.1 Normal operating mode

In the normal operating mode the system will inflate and deflate each cell series every 12 minutes.

The inflation pressure can be changed using the pressure adjustment dial on the power unit; this can be varied between approximately 35mmHg and 60mmHg.

To ensure patients receive effective pressure relief the system should always be set to the 'dynamic' setting.

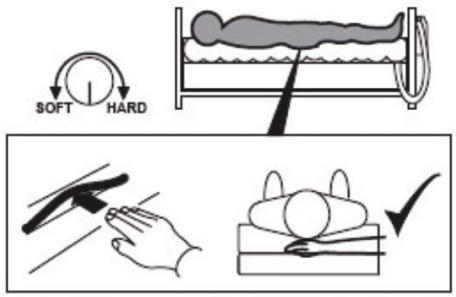
2.2 Setting the optimum pressure

When in dynamic mode all pressures will apply therapy to the user but it is generally accepted that the higher the pressure setting the greater the therapeutic effect, however this may have a trade off in terms of patient comfort. The optimum setting for the patient, balancing comfort against therapy will differ between patients.

Once the patient is in place, use the pressure adjustment dial to reach the desired setting for patient comfort/therapy.

When selecting a lower pressure setting ensure the patient is not 'bottoming out' by sliding a hand under the patient's sacral area (buttocks) when the cell is fully deflated. The patient should be lying flat on their back in a supine position for this assessment (see Figure 7).

Fig 7: Check for bottoming out



Having established a base-line, pressure can be increased to provide added support for the semi-recumbent (sitting up) patient.

NOTE: Wait a minimum of 12 minutes between any pressure adjustment and patient assessment. It will take a full cycle for the system to adjust to the new setting.

2.3 Use of incontinence products

Incontinence products such as sheets or pads can be used with this system. However, product performance is likely to reduce due to the patient experiencing less pressure relief when using these aids.

If incontinence products are to be used it is recommended that regular patient skin checks are performed to ensure skin integrity is maintained.

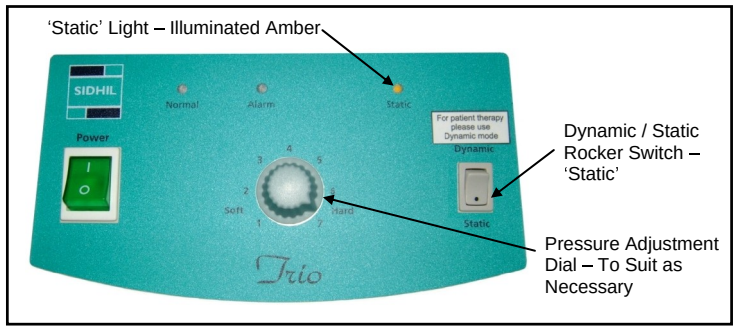
2.5 Static mode

The system has the capability to operate as a static inflated mattress. This function enables nursing staff to carry out procedures on a static support surface and/or to assess the ability of a patient to withstand a static support surface. This is necessary to facilitate patient step down to a non-alternating product.

To select static mode depress the dynamic/static switch to 'static', the 'static' light will now be illuminated amber (see Figure 8).

The pressure can be adjusted to suit using the pressure adjustment dial on the front of the power unit. The Pressure should be reduced when using the static mode to check for a patient's suitability to tolerate a static mattress.

Fig 8: Setting power unit to static mode



Regular patient skin checks should be performed to ensure that a static support surface can be tolerated. Ideally patients should remain on a static support surface for no more than 2 hours without undergoing a thorough skin check. If the patient cannot tolerate static mode the system should be reverted to dynamic therapy by repressing the dynamic/static switch to 'dynamic'. The 'static' light will extinguish and the green 'normal' light will be illuminated. The system will now be operating in dynamic mode.

WARNING

THE STATIC MODE WILL REMAIN OPERATIONAL UNTIL THE STATIC SWITCH IS RETURNED TO THE DYNAMIC POSITION.

WHEN IN STATIC MODE THE PATIENT MUST BE REGULARLY CHECKED FOR SKIN INTEGRITY.

2.6 Transport mode

The transport mode is achieved by disconnecting the four air pipes from the power unit and then connecting them together. Disconnect the pair of pipes with turquoise colour connectors first, then the two single pipes with the

orange and black connectors. The two single pipes snap fit into the dual connection pipes as shown in Figure 9.

Fig 9: Connecting pipes for transport mode

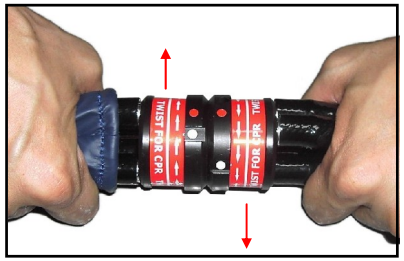
There will be air loss from the system when disconnecting/connecting the pipes for transport mode. The longer it takes to connect the air pipes together the greater the volume of air lost. If the pressure is increased prior to the disconnection the effect of the air loss will be reduced.

Note: the pipes should only be connected together when the mattress needs to be moved whilst remaining inflated. If the user needs to be on a mattress which is not alternating, static mode should always be selected the pipes connected to the power unit.

2.7 Cardio pulmonary resuscitation (CPR)

The mattress can be quickly deflated for CPR. To begin CPR deflation, twist the CPR valve in the direction of the arrows to align the two **red dots**, as shown in figure 10. The mattress will deflate in approximately 30 seconds.

Fig 10: Activating the CPR valve



If required, the mattress can be re-inflated while supporting the patient by twisting the mattress CPR valve back to the original position with the **white dots** realigned. The mattress will then re-inflate in approximately 30

minutes back to its original pressure setting. Note: Until the system re-inflates to the desired pressure the red 'alarm' light will be illuminated.

SECTION 3 ALARMS

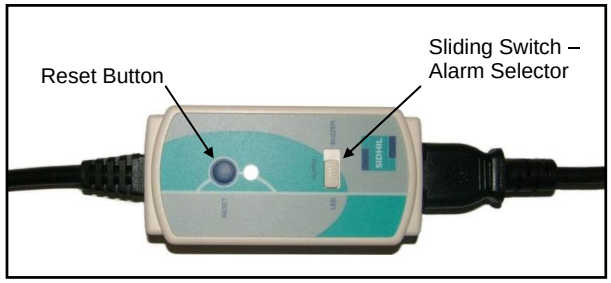
3.1 Power down alarm operation

The power down alarm indicates an interruption in power supply that can be caused by either a mains failure and/or turning off the power unit. The alarm will produce an audible sound and/or a red flashing light. These alarms can be selected by means of a sliding switch (see Figure 11). See Figure 2 for plugging the power down alarm in.

The alarm can/will be cancelled in one of two ways:

- Pressing the reset button on the power down alarm
- Restoring the power supply to the system

Fig 11: Power down alarm



3.2 Low Pressure Alarm

The power unit is fitted with a red alarm warning light to identify low pressure in the mattress. The 'alarm' light will illuminate red if the pressure within the mattress drops below the minimum level. The 'alarm' light will automatically reset once normal operating pressure is reached. Note: the power unit **does not** have an audible alarm.

False alarms may be noticed if a patient has a gross position change or is removed from an inflated mattress. A false alarm will reset itself in a few minutes and should be ignored.

A persistent alarm light indicates a system fault. In this instance see the 'Simple fault finding' section.

SECTION 4 CLEANING

4.1 Infection control

Routine cleaning for infection control must be carried out in accordance with your local infection control policy or regulatory body.

4.2 Cleaning the power unit

WARNING

Disconnect the mains lead from the wall-socket before attempting to clean the unit.

Do not immerse the power unit in water.

Ensure mains lead and power unit are dry before use.

The power unit, mains lead and power down alarm can be cleaned by wiping down with a damp cloth soaked in a 75° Sodium Hypochlorite solution (1000 ppm available chlorine) and dried with a clean dry cloth.

The power unit is not IP rated and care should be taken that only a damp cloth is used.

4.3 Cleaning the mattress

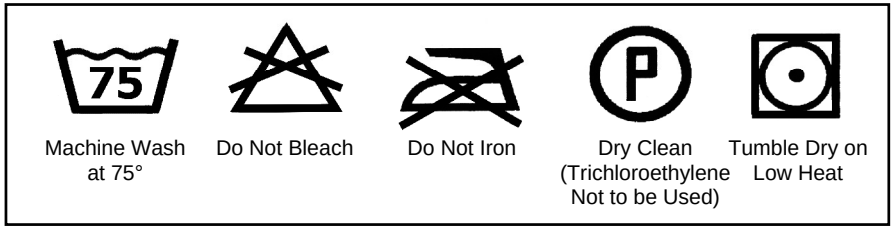
Before attempting to clean the mattress the top cover should be checked for physical signs of damage that may lead to strike-through (ingress of fluid through cover). This is achieved by unzipping the top cover and looking for signs of staining to the white underside. Any evidence of strike-through will require a new cover to be fitted to the system. **The cover must not be reused if strike-through is evident.**

The mattress cover can be wiped down with a 75° Sodium Hypochlorite solution, (1000 ppm available chlorine) and then dried with a clean dry cloth. Alternatively the mattress cover can be machine washed at a temperature not exceeding 75°C and dried either in free air or a tumble drier on a cool setting (see Figure 12).

The cells can be cleaned by deflating the mattress, unzipping the top cover and wiping down the deflated cells with a 75°C Sodium Hypochlorite

solution (1000 ppm available chlorine). Dry the cells thoroughly with a clean dry cloth before use.

Fig 12: Mattress cover cleaning instructions



The mattress, power unit and power-down alarm may also be decontaminated by using ETO (Ethylene Oxide) or the Draeger method.

SECTION 5 SIMPLE FAULT FINDING

Fault	Action
There are no lights showing on the power unit front panel	1. Check that the power unit is switched on
	2. Check that the mains lead is plugged into a working wall socket and the wall socket is switched on. (To ensure socket is working plug in a lamp or other electrical device)
	3. Check that the mains lead is plugged into the power unit
	4. If none of the above work replace fuse in the mains plug (3 Amp 230V)
There are lights showing on the front panel but the mattress fails to inflate	1. Check the CPR valve has the white dots aligned
	2. Check that the mattress is correctly connected to the power unit
	3. Check that all air pipe connectors are snapped fully into place on the power unit
	4. Unzip mattress cover and check all cells are pushed fully onto internal air-pipes
Mattress is not alternating	1. Check power unit is switched on
	2. Check that the dynamic/static rocker switch is set to ‘dynamic’
	3. Check mattress is not in transport mode

If the above actions fail to rectify the problem please contact your local authorised service personnel or Sidhil Limited.

SECTION 6 SERVICING

6.1 Routine servicing

Other than the air filters, there are no user serviceable items within the power unit.

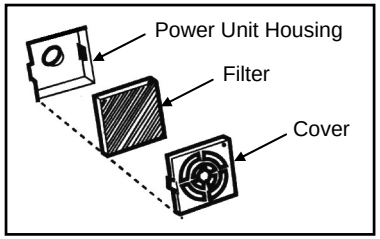
The system should be serviced annually by a qualified service technician. This service can be supplied by Sidhil technicians or alternatively Sidhil can provide appropriate training.

6.2 Air filter replacement

1. Switch off the power unit
2. Disconnect the mains lead and air pipes
3. Place the power unit on a flat surface with its back panel facing upwards (Note: be sure to place a soft cloth under unit to prevent scratching)
4. Carefully remove the air filter covers, remove and discard the filters, replace with new filters and re-fit covers (see Figure 13)
5. The power unit is now ready for use

It is recommended that the air filters are replaced annually.

Fig 13: Air filter removal



6.3 Spare part availability

The annual service requires both air filters to be changed as well as the compressor inlet filter. These components are available as maintenance items. It is recommended that the compressor inlet filter is replaced by a qualified service technician.

Air cells and interchangeable mattress covers can be purchased separately.
For further information please contact the Sidhil customer service staff on 01422 233000 or email sales@sidhil.com

6.4 Serial number locations

The serial number of the power unit is located on the rating plate on the rear of the housing and is contained in the white block in the middle of the unit. The mattress serial number is located on a label inside the mattress at the foot end just above the umbilical entry. The label is sewn into the seam of the bottom half of the cover.

SECTION 7 TECHNICAL SPECIFICATIONS

Mattress

Dimensions	1290mm x 695mm x 100mm (51'' x 27.5'' x 4'')
Weight	4kg (8.8lbs)
Number of Cells	17
Cell Material	Nylon Single TPU coated
Base Material	Nylon TPU coated
Cover Material	Coated polyamide fabric
Mattress Connection	4 x Quick release connectors
CPR Mechanism	'In-line' twist system CPR valve

Power Unit

Dimensions	280mm x 140mm x 125mm (11'' x 5½'' x 5'')
Weight	1.8kg (4lbs)

Power down Alarm

Dimensions	100mm x 50mm x 35mm (4" x 2" x 1.5")
Weight	0.12kg (0.25lbs)

Cycle Time	12 minutes

Supply Voltage	Power unit: 230V, 50Hz, 0.2A Power down alarm: 24~250VAC, 50Hz, 0.01 - 6A
Fuse Rating	Mains plug: 3A Power unit: 1A (x2)
Power Rating	12VA
Electrical Safety Classification	Conforms to EN 60601.1:1996, UL2601 - 1 safety standard Class II, no applied part
Mode of Operation	Continuous
Symbols	~ Alternating current
Mains Switch	I (On) Power connected to the mains supply via power-down alarm 0 (Off) Power disconnected from power-down alarm
Environment (Usage & Storage)	Air humidity 30% to 75% Ambient temperature 0°C (32°F) to 40°C (I04°F)
IP Rating	IPXO
EMC	This equipment complies with EMC requirements. If effects are noticed the affected equipment should be moved apart.

WARRANTY

Sidhil Ltd guarantees this product is free from defects in material and workmanship under normal use for two (2) years from the date of purchase from Sidhil Ltd and its subsidiary companies or its authorised dealers. All implied warranties, including but not limited to those implied warranties of fitness and merchantability, are limited in the total duration of two years from date of purchase. Proof of purchase must be presented with any claim. Except as provided herein, Sidhil Ltd, product warranty does not cover damage caused by misuse or abuse, accident, the attachment of any unauthorised accessory, alteration to the product, or any other conditions whatsoever that are beyond the control of Sidhil Ltd. Sidhil Ltd and its subsidiary companies shall have no liability or responsibility to customer or any other person or entity with respect to any liability, loss or damage caused direct or indirectly by use or performance of the product or arising out of any breach of this warranty, including but not limited to any damages resulting from inconvenience, loss of time, property, revenue, or profit or any indirect, special, incidental or consequential damages, even if Sidhil Ltd or their subsidiary companies or authorised dealers has been advised of the possibility of such damages.

In the event of a product defect during the warranty period you should contact Sidhil Ltd or their authorised dealer who will at its option unless otherwise provided by law; a) correct the defect by product repair without charge for parts and labour b) replace the product with one of the same or similar design or c) refund the purchase price. All replaced parts and products on which refund is made become the property of Sidhil Ltd. New or reconditioned parts and products may be used in the performance of warranty service. Repaired or replaced parts and products are warranted for the remainder of the original warranty period. You will be charged for repair or replacement of the product made after the expiration of the warranty period.

This warranty does not cover; a) damage or failure by or attributes to acts of God, abuse, accident, misuse, improper or abnormal usage, failure to follow instructions, improper installation or maintenance, alterations, lightning or other incidence of excess voltage or current, b) any repairs other than those provided by a Sidhil Ltd authorised technician, c) consumables such as fuses, d) cosmetic damage, e) transportation, shipping or insurance costs or f) costs of product removal, installation setup service adjustment or re-installation.

This limited two year warranty gives you specific legal rights and you may also have other rights.

The company has investigated and tested the suitability of the dynamic pressure therapy systems supplied and manufactured by Sidhil Ltd for various current bed frames and profiling alternatives. However, Sidhil Ltd cannot be held responsible for any injury or incident which relates to the use of the Sidhil dynamic systems in conjunction with products manufactured by companies other than Sidhil Ltd.

All products carry the CE mark in accordance with EC Directive on Medical Devices (93/42/EEC).

Sidhil has a policy of continual product improvement and reserves the right to amend specifications covered in this brochure.

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